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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,113

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Valery Khazhmuratovich Zhilov

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EXAMINER

LEWIS, PATRICK T

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

06/03/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptopatentcommunication@lockelord.com

Office Action Summary	Application No. 10/567,113	Applicant(s) ZHILOV ET AL.	
	Examiner Patrick T. Lewis	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-33 is/are pending in the application.
- 4a) Of the above claim(s) 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28, 29 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the sodium salt of 2-amino-pyrimido[4,5-d]-6H-pyridazine-5,8-dione (Species 1) and sexual disorders/sexual dysfunction (Species 2) in the reply filed on September 19, 2008 is acknowledged.
2. Claims 30-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 19, 2008.

Applicant's Response Dated April 8, 2009

3. Claims 28-33 are pending. Claims 30-32 are withdrawn from consideration. An action on the merits of claims 28-29 and 33 is contained herein below.
4. The rejection of claims 16 and 22 under 35 U.S.C. 112, second paragraph, has been rendered moot in view of applicant's amendment dated April 8, 2009.
5. The rejection of claims 14-16 and 22 under 35 U.S.C. 103(a) as being unpatentable over Yurugi et al. Chem. Pharm. Bull. (1972) Vol. 20, pages 1513-1521 (Yurugi), Zhilov WO 02/09681 (Zhilov), and Goldberg Clinical Therapeutics (1998), Vol. 20, pages 1033-1048 (Goldberg) in combination has been rendered moot in view of applicant's amendment dated April 8, 2009.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 33 recites overlapping terms such as "sexual disorders" and "sexual dysfunction"; "psychoses", "inorganic psychoses", "personality disorders", "psychiatric disorders of mood", "schizophrenia", "bipolar disorders", "neurodegenerative diseases", "Alzheimer's disease", etc.

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8. Applicant's arguments filed April 8, 2009 have been fully considered but they are not persuasive. Applicant argues that claim 33 does not require all of the diseases listed in the claim; however, this argument is not germane. As set forth supra, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 28-29 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yurugi et al. Chem. Pharm. Bull. (1972) Vol. 20, pages 1513-1521 (Yurugi), Zhilov WO 02/09681 (Zhilov), and Goldberg Clinical Therapeutics (1998), Vol. 20, pages 1033-1048 (Goldberg) in combination.

Claims 28-29 and 33 are drawn to a method of treating a disease caused by disorders of nitrenergic system and/or dopaminergic system of an organism comprising administering a cyclic bioisostere of derivatives of a purine system.

Yurugi teaches 2-substituted-5,6,7,8-tetrahydropyrimido[4,5-d]pyridazine-5,8-diones (**6**) having a variety of substituents at 2-position (page 1513; Table II). Among tetraazanaphthalene derivatives a number of pharmacologically active compounds have been known and employed as diuretic agents and cardio-vasodilators.

Yurugi differs from the instantly claimed invention in that Yurugi does not explicitly teach pharmacologically acceptable salts or treating sexual disorders/sexual dysfunction; however, these deficiencies would have been obvious in view of the teachings of Zhilov and Goldberg.

Zhilov teaches a large group of pharmacologically adequate salts of amino-derivatives of 2,3-dihydrophthalazine-1,4-dione which can be used for preventing and treatment of various diseases associated with immunopathologic changes, such as toxicoinfectious, oncologic, allergic and other diseases (pages 1-2). The compounds may also be employed as immunodepressants and immunostimulators.

Goldberg teaches that vasodilators are important in treating male erectile dysfunction (page 1035).

It would have been obvious to one of ordinary skill in the art at the time of the invention treat sexual disorders/sexual dysfunction employing the compounds of Yurugi including pharmaceutically acceptable salts since tetraazaphthalene derivatives are known to function as vasodilators, which are important in treating male erectile dysfunction. A prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.

13. Applicant's arguments filed April 8, 2009 have been fully considered but they are not persuasive. Applicant argues that none of the cited references, alone or combined, disclose treating diseases caused by disorders of the nitroergic system and/or dopaminergic system.

The examiner respectfully disagrees with applicant's assessment and characterization of the prior art. As set forth supra, a prima facie case of obviousness

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may be made when chemical compounds have very close structural similarities and similar utilities. Yurugi teaches 2-substituted-5,6,7,8-tetrahydropyrimido[4,5-d]pyridazine-5,8-diones (**6**) having a variety of substituents at 2-position (page 1513; Table II). Yurugi teaches, "We have been interested in the syntheses of the pyridazine-containing tri- and tetraazanaphthalene derivatives to test their pharmacological activities because 1-hydrazinophthalazine (hydralazine) is well known as hypotensive agent." Hypotension refers to an abnormally low blood pressure which is most often associated with reduced blood volume. Vasodilation refers to the dilation of blood vessels which leads to increased blood flow. Goldberg teaches that vasodilators are important in treating male erectile dysfunction (page 1035). It would have been obvious to one of ordinary skill in the art at the time of the invention treat sexual disorders/sexual dysfunction employing the compounds of Yurugi including pharmaceutically acceptable salts since tetraazanaphthalene derivatives are known to function as vasodilators, which are important in treating male erectile dysfunction.

Conclusion

14. Claims 28-33 are pending. Claims 30-32 are withdrawn from consideration. Claims 28-29 and 33 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-

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0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patrick T. Lewis/
Primary Examiner, Art Unit 1623

/PL/